DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Services**

Memorandum

Food and Drug Administration
Center for Biologics Evaluation and Research
Bethesda, M D. 20892.

Date: 19/12/95

From: Julia Goldstein, DMA.

Through: Katy Stein, DMA. K.E. Stein

To: Chris Joneckis, DARP.

Reference: PLA 94-0308, Verluma ™ .

Sponsored : Dr. Karl Thomae GmbH.

I have reviewed the stability data submitted by Dr. Karl Thomae GmbH for the Fab fragment NR-LU-10, which is one of the [redacted] component of the Verluma™ Kit.

In reference to:

1)The final vialed product:

The sponsor submitted stability data of the following batches:

- NF 2435 Lo03 B (from formulated bulk lot 9447/1) a[redacted] for a [redacted] period,
- NF 3435 Lo02 (from formulated bulk 18405) at [redacted] for a [redacted] period,
- 30001 (from formulated bulk18407) at [redacted] for a [redacted] months period.

The results are consistent and conformed specifications.

2) The hold [redacted]

The sponsor submitted stability data of batch 18006 at [redacted] for a period of [redacted] months.

3) The hold [redacted]

The sponsor submitted stability data at [redacted] for batches 18002 and 18003 for the period of [redacted] months, and for batch 9447/1 the stability data was determined a [redacted] for [redacted] months.

4) The Formulated Bulk:
The stability of the formulated bulk was determined on lots 9447/1,18402 and 18407 at [redacted] for a [redacted] months period.

In summary:

The data submitted supports stability of the the final product (Fab) at [redacted] for [redacted] months. For the [redacted] step and for the formulated bulk, the data supports storage at [redacted] Although the sponsor submitted stability data of one lot for the [redacted] step, this step occurs before fragmentation and all down-stream purification and testing. Therefore, [redacted] seems reasonable, even based on one lot.